Long-Term Use of Standard Days Method®: Experience of Operations Research Study Participants

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The purpose of the AWARENESS Project was to improve contraceptive choices by expanding natural family planning options and developing new strategies and approaches to increase the reproductive health awareness of individuals and communities in developing countries.

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Executive Summary

This long-term follow-up (LTFU) study sought to learn more about Standard Days Method® (SDM) use beyond the six or 12 month follow-up period of a series of 14 operations research (OR) studies in six countries. The LTFU study followed participants of OR studies in Benin, Ecuador, Honduras, and two sites in India for up to 24 additional months to determine long-term continuation and effectiveness patterns, reasons for discontinuation, and whether women use the SDM to achieve pregnancy if their fertility intentions change. The 1,183 participants represented wide variability in geographic location, service delivery mode, age, parity, education level and ever use of contraception. Significant loss to follow-up at the point of transition between the OR and LTFU studies and the retrospective nature of the LTFU questions were taken into consideration in data analysis.

The percentage of women continuing to use the SDM after one year ranged from 23 to 61. The typical-use pregnancy rate for the first year varied from 7.92 (urban India) to 25.4 (Ecuador), with an overall first-year pregnancy rate of 14.13, comparable to the pregnancy rate of 12 found in the SDM efficacy study. The wide variability of these results, even within the same country, suggests the potential influence of both service delivery and user characteristics, including quality of screening and counseling and user motivation to avoid pregnancy. In addition, at the participants' last cycle in the study, 12% of participants in Ecuador, 48% in Honduras, and 85% in India had transitioned from using CycleBeads® to calendars or other means to track their fertile days.

Major reasons for leaving the study were loss to follow-up and out-of-range cycles. The proportion of women becoming pregnant or with a second out-of-range cycle is significantly smaller in the second and third year of the study, confirming that women are more likely to become pregnant in the first few months of method use and less likely to have cycles out of range after the first year.

In the Benin site—the only site to collect such data—37% of participants who said their pregnancy was planned reported using the SDM to become pregnant.

The service delivery experience gained during these studies was used to refine and improve SDM service delivery protocols, materials and training approaches on over 25 countries.

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ACRONYMS

CASP	Community Aid Sponsorship Program
CEDPA	Centre for Development and Population Activites
CEMOPLAF	Centro Médico de Orientación y Planificación Familiar
FBOs	Faith–Based Organizations
IRH	Institute for Reproductive Health
LTFU	Long-Term Follow-up
MOH	Minstery of Health
NGO	Non-governmental Organization
OR	Operations Research
SDM	Standard Days Method®
USAID	United States Agency for International Development

1. BACKGROUND

The Standard Days Method® (SDM) is a simple fertility awareness-based method of family planning. To prevent or delay pregnancy, users of the SDM avoid unprotected intercourse on days 8 to19 of the cycle (inclusive). The method works best for women with cycles that usually range between 26 and 32 days.

The SDM was developed and tested by the Institute for Reproductive Health, Georgetown University (IRH). This process included establishing theoretical effectiveness, conducting an efficacy trial, and implementing a series of operations research (OR) studies to learn about service delivery strategies as well as to test in different areas of the world the acceptance, continuation, and effectiveness of this new method of family planning.

The objective of this long-term follow-up study (LTFU) was to learn about long-term use of the SDM, beyond the six or 12 month follow-up period of the OR studies. The findings of this study cannot be used to calculate continuation rates for SDM users, as (1) women previously had been enrolled in an OR study, accounting for up to one year of method use, (2) in some sites there was a hiatus between the OR study and the beginning of this study, and (3) the study periods ended before all participants had the opportunity to complete it. However, results suggested that method continuation for SDM is at least as good as for other user-controlled methods. This research, conducted by IRH, was funded by the United States Agency for International Development (USAID).

1.1. SDM

SDM was designed to provide a simple, easy way for women to determine their fertile days. It is based on the fact that there is a 12-day fertile window during a woman's menstrual cycle during which she can, with varying degrees of likelihood, become pregnant from unprotected intercourse. For women whose cycles usually range between 26 and 32 days long, this window is from day eight through day 19 of their cycles and users avoid unprotected intercourse on these days. Effective method use requires cooperation of both members of the couple. A multi-site efficacy study found the SDM to be highly effective. The correct-use pregnancy rate was 4.75; the typical use pregnancy rate was 11.96[1]. Following the efficacy study, a series of 14 OR studies were conducted in six countries to test the introduction of the SDM into different service delivery strategies.

1.2. Justification

The OR studies were designed to follow women for up to 13 cycles of method use. However, slow recruitment and limited time resulted in the termination of some studies before all participants completed the 13 cycles. Further information was needed about

[1]Arevalo M, Jennings V, and Sinai I (2002). Efficacy of a New Method of Family Planning: the Standard Days Method. *Contraception* 65:333-338.

longer-term use of the method. The LTFU study was designed to fill this gap, by following participants of some of the OR studies for an additional period of up to two years.

1.3. The OR Studies

The OR studies were designed to assess the feasibility and acceptability of offering the SDM in diverse cultural and service delivery settings. An element of the design was the collection of prospective data from SDM users in order to determine correct use, acceptability, and satisfaction with the SDM in settings that more closely resemble regular service delivery than was possible during the efficacy study. In addition, these studies provided information on other research questions associated with SDM introduction. In Ecuador and the Philippines, the potential for offering the SDM in a single counseling session versus two sessions was compared. Integration of the SDM into water and sanitation programs was tested in El Salvador. In India and the Philippines, strategies to reach men were tested. Integration of the SDM into different types of service delivery contexts such as the Ministry of Health (MOH), private non-governmental organizations (NGO) and faith-based organizations (FBOs) were compared in Honduras, Benin, and the Philippines. Willingness-to-pay data were collected from study participants in Ecuador and the Philippines. Expanding informed choice and changes in provider attitude were measured in Honduras and Ecuador[2, 3].

2. METHODOLOGY

The LTFU study followed OR participants in study sites in Benin, Ecuador, Honduras, and two sites in India. These settings represented wide variation. In Ecuador, the SDM was offered by Centro Médico de Orientación y Planificación Familiar (CEMOPLAF), a family planning NGO, which offered both clinic-and community-based services. The method was offered in Honduras in MOH primary care centers and by community health workers affiliated with Catholic Relief Services. The study site in Benin was a maternity hospital with dedicated family planning clinics. In India, the method was offered by CARE, which operates a reproductive health program in rural villages in Uttar Pradesh, and by the Community Aid Sponsorship Program (CASP), in conjunction with Centre for Development and Population Activities (CEDPA), which works in urban slums in Delhi.

LTFU participants were followed periodically for up to two years of method use, starting when they exited the OR studies either because they completed 13 cycles of method use or because the study ended. The study protocol, procedures and instruments were approved by the Institutional Review Board of Georgetown University. The LTFU study was designed to answer the following questions:

- What are the long-term continuation patterns of SDM use?

[2] Lundgren RI., Gribble JN, Green ME, Emric GE, and de Montoy M (2005). Cultivating men's interest in family planning in rural El Salvador. *Studies in Family Planning* 36(3):173-188.

[3] Gribble JN, Lundgren RI, Velasquez C, and Anastasi EE (2007). Being strategic about contraceptive introduction: the experience of the Standard Days Method. *Contraception*, (forthcoming)

- What is the long-term effectiveness of the SDM?
- Why do women stop using the SDM?
- When the fertility intentions of women who had used the method to avoid pregnancy change, do they use the SDM to achieve a pregnancy?

2.1. Study design

The LTFU study was developed when the OR was already underway, and in some sites after it was completed. Therefore participants had to be re-admitted after they completed the OR study, and they needed to sign a new informed consent form. This resulted in delays in admissions to the LTFU study and in loss of some participants to follow-up. Some 3 to 9 months after exit from the OR women were re-contacted and were invited to participate in the LTFU study. They were admitted to the study after signing the informed consent form.

Follow-up questionnaires were administered at 3-, 6-, 12-, 18-, and 24- month follow-up interviews. Each interview lasted approximately 15 to 20 minutes and was similar to those used in the OR studies. Because of the delay in setting up the study, some women were not contacted until more than six months had passed from their exit interview. In these cases the 3-month follow-up was skipped. At each interview participants were administered one of three questionnaires:

- *Standard follow-up, to determine if participant was still using the SDM*. This form included questions about current use of the SDM, CycleBeads® use, reproductive intentions, and use of other family planning methods. It also asked about change in pregnancy status and pregnancy intentions in the previous 3-6 months.
- *Pregnancy form, administered to participants who self-reported pregnancy*. This form included questions on reproductive intentions, use of the SDM at the time of conception, and future use of the SDM.
- *Discontinuation form*, *administered if a participant indicated at previous interview that she was no longer using the SDM.* She was asked if she had begun using the SDM again, and questions about current use of a family planning method and pregnancy status.

A full set of the questionnaires (in English) is attached as Appendix A, B and C. It was translated to local languages as needed.

To help with data management, participants retained the identification codes they were assigned in the OR studies. All participants were listed on a participant tracking form, which was used to track their progress through the study. A separate form was used to track loss-to-follow-up. If the woman could not be found after three attempts, or if the interviewer obtained information that the woman had moved away from the area permanently, the participant was classified as lost to follow-up.

2.2. Data management and analysis

Data was entered into SPSS in each country, and the local research teams prepared preliminary analyses and reports. The data were then sent to IRH, where they were checked for consistency, and re-coded as needed so that the individual datasets would be compatible for shared analysis.

Analysis for this report was done in SPSS and Excel. Frequencies and cross tabulations were used for descriptive data; multi-censoring life tables were used to calculate pregnancy rates. This methodology was ideal because it treats each time period independently. Therefore the high proportion of women who left the study prematurely did not influence the analysis.

The approach was to view the OR phase and the LTFU phase of the studies as a continuum. For example, a woman who left the study after ten months of method use while the OR study was in progress, and a woman who left the study after ten months of method use but was already enrolled in the LTFU, are not distinguished. For each time period, IRH determined how many participants were using the SDM at the beginning of the time period, how many left the study during the study period, and how many became pregnant. Women who left the study during a time period were considered to have contributed half of the time period.

3. RESULTS

A total of 1183 participants are included in the analysis, after excluding cases for which the research team could not determine the approximate length of SDM method use, either because information was missing on the woman's entry or exit dates, or because mistaken coding prevented connecting the OR data (entry date) with the LTFU data (end date) for that woman. Table 1 shows the number of participants in each study site.

Table 1: Participants per site

Country	Participants
Benin	217
Ecuador	160
Honduras	108
India (CARE)	479
India (CASP)	217
Total	1183

3.1. Client profile

Table 2 presents the characteristics of study participants, by country. Figures are drawn from admissions data and from OR study reports.

Table 2: Client profile

	Benin	Ecuador	Honduras	India (CARE)	India (CASP)
Age (mean)	(30.3)	(29.5)	(28.5)	(28.8)	(28.4)
<20	14.9	5.0	7.3	3.8	0.9
20-24	17.8	23.0	23.9	15.6	18.2
25-29	19.2	24.8	24.8	30.6	37.8
30-34	22.1	24.2	27.5	28.8	28
35-39	13.0	14.3	11	17.7	14.7
40+	13.0	8.7	5.5	3.5	0.4
Formal education					
None	15.0	3.6	0.9	55.2	49.8
Some primary	32.0	24.8	27.5	17.2	22.2
Some secondary +	52.9	71.6	71.6	27.6	28.0
Parity (mean)	(3.2)	(1.8)	(1.9)	(3.8)	(2.8)
0 children	19.7	11.3	8.3	3.3	2.6
1-2 children	42.5	66.2	64.8	30.1	37.8
3-4 children	26.4	19.4	24.1	45.0	50.0
5+ children	11.4	3.1	2.8	21.6	9.6
Ever use of contraceptives					
None	54.8	18.2	20.2	47.5	27.6
Periodic abstinence	39.3	33.9	28.4	9.0	0.4
Withdrawal	7.3	10.3	11.9	0	0.9
Condoms	20.1	22.4	36.7	43.0	65.8
Pills	5.5	37	39.7	0.5	5.8
Injectables	3.2	21.2	31.2	0	0
IUD	0	40	23.9	0	6.2
Other	5.0	3.6	1.7	0	0

These data demonstrate the variability of the study sites. Women in Benin and Ecuador were older, on average, then women in Honduras and India; parity is highest in India and Benin; education level and ever use of family planning also vary.

3.2. Continuation and exits

LTFU data cannot be used to calculate continuation rates because they are heavily influenced by the large proportion of women who were not enrolled in the LTFU study when their OR study ended during the first year of method use (because of the delay in starting the LTFU study). Benin and India (CASP) were the only sites where most participants completed 13 cycles of method use, or left the study for a non-study reason, before the OR study ended (61.2% of women in Benin and 53.5% in India [CASP] were still using the method after 13 cycles). In addition, women were enrolled in the LTFU for two years regardless of how long they had been in the OR study. Therefore women who moved from OR to LTFU before 13 cycles of method use had no opportunity to participate in the study for the maximum three years.

Table 3 shows reasons for leaving the study by country and by year. Cells with n<30 were left blank because of their small size. Note that there was significant loss to follow-up at the point of transition between OR and the LTFU study. These women left because the study ended (and the LTFU study had not yet begun), but it is impossible to distinguish between them and actual lost-to-follow-up. Also, some participants coded as 'exited for another reason' left the study because the study ended, but information is not always available to make this distinction.

Reasons for leaving the study other than pregnancy or cycles out of range were not always provided, but they include change of fertility intentions (desire for pregnancy), marital dissolution, migration (leaving the study but continuing to use the method), and some preference for method switching.

Table 3: Reasons for leaving the OR/LTFU studies (% of exits during year)

		Benin	Ecuador	Honduras	India (CARE)	India (CASP)	Total
Year 1	**Completed 3 years**	0	0	0	0	0	0
	Study ended	0	16.3	5.3	0	51.0	11.2
	Lost to follow up*	21.2	31.7	26.7	25.3	27.7	26.5
	Cycles out of range	12.9	21.1	20.0	27.1	6.9	19.6
	Pregnant (planned)	0	8.1	4.0	7.2	0	4.8
	Pregnant (unplanned)	27.1	22.8	18.7	15.4	11.9	17.4
	Left for other reason	38.8	0	25.3	25.0	2.5	20.4
	n*	85	123	75	332	159	774
Year 2	**Completed 3 years**	0	n is too	n is too	0	n is too	0
	Study ended	0	small	small	0	small	9.9
	Lost to follow up	9.3			0		15.9
	Cycles out of range	7.4			12.9		6.0
	Pregnant (planned)	13.0			22.6		15.9
	Pregnant (unplanned)	11.1			12.9		8.6
	Left for other reason	59.3			51.6		43.7
	n	54	23	18	31	25	151
Year 3	**Completed 3 years**	15.4	n is too	n is too	26.5	72.7	28.7
	Study ended	11.5	small	small	53.0	0	27.9
	Lost to follow up	2.6			0	27.3	5.0
	Cycles out of range	10.3			0	0	3.1
	Pregnant (planned)	6.4			4.3	0	5.0
	Pregnant (unplanned)	6.4			6.0	0	5.8
	Left for other reason	47.4			10.3	0	24.4
	n	78	10	15	117	33	258

* n is the number of exits per country per year

Table 4 shows participants who left the study because they had cycles out of the 26-32 day range. Clearly the proportion of women with a second out-of-range cycle is significantly smaller in the second and third year of the study, confirming that women who 'survive' the first year of SDM use are less likely to have cycles out of range.

Table 4: Participants with a second out-of-range cycle per year, as a percentage of the number of participants who were using the method at the beginning of that year

	Benin	Ecuador	Honduras	India (CARE)	India (CASP)	Total
Year 1						
Cycles out of range	5.1	15.6	13.9	18.8	5.1	12.9
n at start of year	217	160	108	479	217	1181
Year2						
Cycles out of range	3.0	2.7	0	2.7	0	1.9
n at start of year	133	37	36	146	116	468
Year3						
Cycles out of range	10.3	n too small	n too small	0	0	2.5
n at start of year	78	14	18	118	88	316

3.3. Effectiveness of the SDM

Table 5 shows unplanned pregnancies by country and year. The proportion of women who become pregnant is significantly smaller in the second and third year of use than in the first, confirming findings from earlier studies that show that most women who become pregnant while using the SDM do so in the first few months of method use.

Table 5: Unplanned pregnancies per year as a percentage of participants who were using the method at the beginning of that year

	Benin	Ecuador	Honduras	India (CARE)	India (CASP)	Total
Year 1						
% pregnant	10.6	17.5	13.0	10.6	8.8	11.4
n at start of year	217	160	108	479	217	1181
Year2						
% pregnant	4.3	2.7	5.6	2.7	0	2.8
n at start of year	133	37	36	146	116	468
Year3						
% pregnant	6.4	n too small	N too small	5.9	0	4.7
n at start of year	78	14	18	118	88	316

IRH used multi-censoring life-tables to calculate pregnancy rates. The typical-use pregnancy rate for the first year per country is shown in Table 6. Table 7 shows combined pregnancy rates (all countries) per year of use.

Table 6: First year pregnancy rates

	Cycle	Women exposed	Pregnancies	Pregnancy rate	95% confidence interval
Benin	1	209	3	1.44	0.19 to 3.03
	4	187	8	5.65	2.35 to 8.85
	7	169.5	6	8.99	4.81 to 12.99
	10	151.5	4	11.39	6.66 to 15.89
	13	138	2	12.68	7.67 to 17.42
Ecuador	1	152	14	9.21	4.49 to 13.69
	4	100.5	4	12.82	7.02 to 18.26
	7	72.5	8	22.44	13.98 to 30.07
	10	52.5	2	25.40	16.16 to 33.62
	13	40.5	0	25.40	16.16 to 33.62
Hondura s	1	105	7	6.67	1.77 to 11.32
	4	79.5	5	12.54	5.58 to 18.98
	7	60.5	1	13.98	6.52 to 20.85
	10	45	0	13.98	6.52 to 20.85
	13	38.5	1	16.22	7.60 to 24.03
India (CARE)	1	474	10	2.11	0.81 to 3.39
	4	419	17	6.08	3.83 to 8.28
	7	328.5	10	8.94	6.12 to 11.67
	10	250	13	13.68	9.96 to 17.23
	13	168	1	14.19	10.36 to 17.86
India (CASP)	1	216.5	6	2.77	0.56 to 4.93
	4	185.5	2	3.82	1.18 to 6.39
	7	164	7	7.92	3.96 to 11.72
	10	135.5	0	7.92	3.96 to 11.72
	13	121	0	7.92	3.96 to 11.72

Table 7: Overall pregnancy rates by year

	Cycle/month	Women exposed	Pregnancies	Pregnancy rate	95% confidence interval
Year 1	Cycle 1	1156.6	40	3.46	2.40 to 4.51
	Cycle 4	971.5	36	7.04	5.49 to 8.55
	Cycle 7	795	32	10.78	8.81 to 12.70
	Cycle 10	634.5	19	13.45	11.20 to 15.65
	Cycle 13	506	4	14.13	11.80 to 16.41
Year 2	Month 4	456	2	0.44	0 to 1.04
	Month 7	431.5	3	1.13	0.14 to 2.11
	Month 10	400	6	2.61	1.08 to 4.13
	Month 13	352.5	4	3.72	1.85 to 5.56
Year 3	Month 4	306	10	3.27	1.26 to 5.24
	Month 7	264.5	3	4.37	2.01 to 6.66
	Month 10	214.5	2	5.26	2.61 to 7.83
	Month 13	145.5	1	5.91	2.98 to 8.75

Couples can use the SDM not only to avoid pregnancy, but also to plan a pregnancy. In the Benin site, 37% of the participants who said their pregnancy was planned said they used the SDM to become pregnant. This information suggests that SDM users who decide to have another child sometime use the SDM for that purpose. Information on the use of SDM to achieve pregnancy was not collected in the other sites.

3.4. Use of CycleBeads

CycleBeads are a mnemonic aid that helps women keep track of which cycle day they are on and of their cycle length and facilitates partner communication about the fertile days. The use of CycleBeads varied by country. In some settings, it appears that a number of experienced SDM users transitioned from using CycleBeads to calendars or other means to track their fertile days. The research team's review of participants' last cycle in the study shows that 12% of participants in Ecuador and 48% in Honduras were no longer using CycleBeads, compared to 85% in India (CARE).

3.5. Validity of the results

Several methodological issues may impact the validity of the results, as follows:

- The need to collect LTFU information became apparent in the later stages of the OR studies, and the decision to conduct the study was made after the OR study was already completed in some sites. In these settings, many participants had already completed 13 cycles of method use and exited the study. As a result, the transition from OR to LTFU was not smooth, many potential participants were lost to follow-up, others did not contribute data for the transition cycles, and most participants did not have the opportunity to contribute three years to the study.
- Data were collected every 3 to 6 months. Therefore questions were asked retrospectively of women for each time period. The accuracy of the results depends on recollection. Also, perception of pregnancy as planned or unplanned may have been influenced by the passage of time.
- While all study sites used the same study forms, some questions were interpreted differently by the various research teams.
- Loss-to-follow-up was determined after several attempts to find the woman. The date in which she was determined lost is not the last date for which information on her is available, because the unsuccessful attempts to find her occurred when it was time to interview her again, 3-6 months after her last interview
- When a woman said she was pregnant, she was asked how long she had been pregnant. The team depended on the accuracy of her response to determine the time-period in which she was exposed to the risk of pregnancy. This was not always straight forward. For example, if she said that she was three months pregnant during her month 18 interview, did conception occur during the 15-18 month period, or during the 12 to 15 period? Much depended on the exact date of the interviews.

To minimize bias due to these issues the researchers were consistent with interpretation of the figures. IRH developed guidelines to determine transition points and used them consistently across all women and all sites. The results for individual women may not be accurate, but any inconsistencies will cancel each other out in the aggregate and across sites.

4. DISCUSSIONS AND CONCLUSIONS

This study provides data on SDM use over time for 1183 women from diverse service delivery settings in six countries in Africa, Asia and Latin America. The percent of women continuing to use the SDM after one year ranged from 23 to 61%. This variation suggests the potential influence of service delivery and user characteristics on utilization of user-dependent methods. The major reasons for leaving the study were loss to follow-up and out-of-range cycles. The proportion of women with a second out-of-range cycle was significantly smaller in the second and third year of use, confirming that women who 'survive' the first year of SDM use are less likely to discontinue use due to cycle length. Similarly, the proportion of women who become pregnant was significantly smaller in the second and third year of use.

The typical-use pregnancy rate for the first year varied from 7.92 (urban India) to 25.4 (Ecuador). The overall pregnancy rate for the first year was 14.13, comparable to the pregnancy rate of 12 found in the efficacy study. The size of the combined sample and the variability of sites contribute to stronger results, despite the methodological limitations of retrospective data collection.

The variability of these results, even within the same country, suggest that service delivery factors such as the quality of screening and counseling and efforts to inform men of their role in method use, as well as user factors such as motivation to avoid pregnancy, may influence typical use pregnancy rates.

The service delivery experience gained during these studies was used to refine and improve SDM service delivery protocols, materials and training approaches. These improved approaches are now being used in over 25 countries around the world.

Five years of SDM service delivery, combined with the availability of settings in which the SDM is an established part of family planning programs, provide opportunities for further research on the patterns of SDM use. Of particular interest would be research in settings where comparable prospective data can be collected from women using different user-dependent methods, offered within the same training and service delivery structure. In addition, further research may be warranted on the utility of the SDM in helping couples seeking to achieve pregnancy.

Addendum A

Long-term Follow-Up Study
Standard Follow-up Questionnaire

Circle appropriate interview:

3 month 6 month 12 month 18 month 24 month 30 month 36 month

Background information – date of last interview, participant ID code, etc. as used in other instruments.

1. Record date LMP (based on review of participant's calendar):
   _____/_____/_____

2. Since we last spoke three/six months ago, have you been pregnant or think you have been pregnant, but are not pregnant now?
   1____Yes, was pregnant
   2____Might have been pregnant but not sure
   3____No, was not pregnant

3. Are you still using necklace every day?
   1____Yes → Skip to Q.5
   2____Sometimes
   3____No

4. Are you using the necklace at all?
   1____Yes
   2____Sometimes
   3____No → Skip to Q.10.

5. Do you move the black ring every day?
   1____Yes
   2____No

6. Do you plan on using it for the next 3-6 months?
   1____Yes
   2____No

7. Are you interested in becoming pregnant during the next 6 months?
   1____Yes
   2____No → Skip to Q.9.
   3____Not sure → skip to Q.9.
   4____Depends (write response_____)

8. To become pregnant, are you more likely to stop using the necklace completely or to use it less often?

1____Stop completely
2____Use it less often

9. During your fertile days, what do you do to avoid pregnancy? Write response.

All responses →Skip to Q.16.

10. What are the main reasons you stopped using the necklace (mark all that apply)
    1____Irregular cycles
    2____Woman doesn't like method or cannot comply
    3____Partner doesn't like method or cannot comply
    4____Think method is not effective
    5____Wants to become pregnant
    6____Marital dissolution
    7____Other (specify _____)

11. When did you stop using the necklace? (approximate date)

12. Are you doing something to avoid becoming pregnant?
    1____Yes → skip to Q.15.
    2____No (Remind participant that provider may be able to give a different method, if she wants one.)

13. Why not? Write response

14. What are you doing to avoid becoming pregnant? Write response

15. Date/time of next interview

16. Observations/comments

If response to Q3 is "No", at next follow-up interview, use "Former User Instrument."

Appendix B

Long-term Follow-up Study
Pregnancy Questionnaire

Circle appropriate interview:

3 month 6 month 12 month 18 month 24 month 30 month 36 month

Background information – date of last interview, participant ID code, etc. as used in other instruments.

1. Approximately how many months ago did you get pregnant?

2. Did you stop using the necklace before you got pregnant or after?
    1. _____ Before
    2. _____ After→skip to Q.6.

3. Why did you stop using the necklace?
    1. _____ Irregular cycles
    2. _____ Woman doesn't like method or cannot comply
    3. _____ Partner doesn't like method or cannot comply
    4. _____ Thinks that method is not effective
    5. _____ Wants to become pregnant
    6. _____ Marital dissolution
    7. _____ Other (specify:_____)

4. After you stopped using the necklace, did you use any other method?
    1. _____ Yes
    2. _____ No→ skip to Q.8.

5. Which method did you use? Write response.

    → **All responses to Q.5.—Skip to Q.8.**

6. When you had sex during fertile days, did you use another method together with the necklace?
    1. _____ Yes
    2. _____ No→ Skip to Q.8.

7. Which method(s) did you use? Write response.

8. Do you think you might use the necklace method again in the future?
    1. _____ Yes → Skip to Q.10.
    2. _____ No

9. Why not? Write response.

10. Observations/comments

    Thank woman for participating in follow-up study. Remind her of the importance of obtaining prenatal care. Tell her where she can obtain prenatal care.

Appendix C

Long-term Follow-up Study
Discontinued User Questionnaire

If woman had stopped using necklace at time of the most recent follow-up interview (the interview that came immediately before this one), use this questionnaire.

Circle appropriate interview:

3 month 6 month 12 month 18 month 24 month 30 month 36 month

Background information – date of last interview, participant ID code, etc. as used in other instruments.

1. Are you currently pregnant or have you been pregnant since we last talked?
   1____Currently pregnant → skip to Q.9.
   2____Has been pregnant but is currently not pregnant
   3____Has not been pregnant and is currently not pregnant

2. Have you started using the necklace again?
   1. _____ Yes
   2. _____ No→skip to Q.5.

3. Why did you start using the necklace again?

4. How many months ago did you start using the necklace again?
   → Skip to Q.11.

5. Are you currently using another family planning method?
   1. _____ Yes
   2. _____ No→ skip to Q.8.

6. Which method are you currently using? Write response.

7. Are you satisfied with your current method of family planning?
   1. _____ Yes
   2. _____ No

Appendix C

8. Have you thought about using the necklace method again at some time in the future?
    1. _____ Yes → Skip to Q.11.
    2. _____ No → Skip to Q.11.

9. Were you using a family planning method when you got pregnant?
    1. _____ Yes
    2. _____ No → Skip to Q.11.

10. What method were you using? Write response.

11. Comments/observations

    If woman has started using necklace again, continue to interview her in follow-up study.

    Date and time of next interview:

    If woman has not started to use necklace again, thank woman for participating in follow-up study.